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510(k) SUMMARY
Summary of Safety and Effectiveness
Abbreviated 510(k) Submission

1.- Submitter Information

Applicant:	Biotrac, Inc.
Address:	7215 N.W. 46th Street Miami, FL 33166 USA
Telephone Number	(305) 594-7474
Fax Number	(509) 267-2283
Contact Person:	Jaime Guttman Biotrac, Inc. 7215 NW 46th Street, Miami, FL 33166 (305) 594-7474 (Phone) (509) 267-2283 (Fax)
Contact Title:	Director
Contact e-mail:	jaime@biotracmed.com

2.- Name of Device

Trade Name:	ABP-2000 G-3
Common Name:	Ambulatory Blood Pressure Monitor
Classification name:	21 CFR 870.1130 Non-Invasive Blood-Pressure Measurement System (DXN). Class II, Circulatory System Devices Panel (74)

3.- Predicate Devices

K012647, Tonoport V, PAR Medizintechnik GmbH.
K003004, Oscar 2, SunTech Medical Instruments.
K964235, ABPM Mobil-o-Graph Blood Pressure Monitor, I.E.M. GmbH.

The ABP-2000 G-3 is substantially equivalent to these devices.

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4.- Device Description

The ABP-2000 G-3 is an automated, ambulatory, non-invasive blood pressure (NIBP) monitor microprocessor based. The device uses an oscillometric linear deflation technique to determine blood pressure. A cuff is inflated by an internal electrical air pump, and the deflation process is controlled by two internal valves. During deflation, the arterial blood pressure pulses are sensed by the device by means of cuff pressure changes, which are analyzed by the microprocessor in order to determine the blood pressure. The ABP-2000 G-3 can record patient's blood pressure at different and previously determined intervals as clinically scheduled, or can be activated by pressing the Start/Stop button.

The physician can program the measurement intervals as well as the LCD display (it can be disabled to prevent patient from seeing the readings) and then, the device is placed on the patient at the physician's office and is usually worn for 24 hours. The ABP-2000 G-3 software allows the physician to setup the device, the display and to keep all the records. The information is stored on an internal memory that will register each reading. All the data can be downloaded (via serial cable) into the computer software once the study has ended. The information can be analyzed and presented in either graphical or table format, and printed in either format using the PC software.

5.- Intended Use

It is intended to be used as an aid or support for the initial diagnosis and subsequent treatment's follow-up when it is necessary to measure a patient's blood pressure over a determined period of time. The system does not make any diagnose, it only measures, stores and displays the information. The ABP-2000 G-3 (NIBP) monitor is only intended and designed:

- for measuring the systolic, diastolic and mean blood pressure as well as the heart rate of human beings.
- for recording during a predetermined period of time the above mentioned measurements (up to 250 measurements).
- to be used along with the ABP-2000 G-3 software for programming as well as record keeping and display in a graphical or tabular report.

6.- Technology

The ABP-2000 G-3 uses the same functional technology employed by the predicate devices.

7.- Performance

The ABP-2000 G-3 has been approved according to the British Hypertension Society's protocol. The device complies with all of the requirements of the AAMI SP-10.

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8.- Conclusion

The ABP-2000 G-3 performs as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

Biotrac, Inc.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

Re: K021029
Trade Name: ABP-2000 G-3
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: February 21, 2002
Received: March 29, 2002

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Abbreviated Submission
ABP-2000 G-3
Biotrac, Inc. Miami, FL

Indications for Use Statement

510(k) Number (if known):

Device Name: ABP-2000 G-3 (Non-Invasive Ambulatory Blood Pressure Monitor)

Indications for Use: It is intended to be used as an aid or support for the initial diagnosis and subsequent treatment's follow-up when it is necessary to measure a patient's blood pressure over a determined period of time. The system does not make any diagnose, it only measures, stores and displays the information. The ABP-2000 G-3 (NIBP) monitor is only intended and designed:
- for measuring the systolic, diastolic and mean blood pressure as well as the heart rate of human beings.
- for recording during a predetermined period of time the above mentioned measurements (up to 250 measurements).
- to be used along with the ABP-2000 G-3 software for programming as well as record keeping and display in a graphical or tabular report.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021029

Prescription Use X
(Per 21 CFR 801.109)